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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/343,943	06/30/99	KNOWLTON	E 16904-738

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EXAMINER
GIBSON, R

ART UNIT	PAPER NUMBER
3739	8

DATE MAILED: 09/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/343,943

Applicant(s)

KNOWLTON, EDWARD W.

Examiner

Roy D. Gibson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-5 and 7-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 34 and 35 is/are allowed.
- 6) ☐ Claim(s) 1-5, 7, 8, 10-22 and 30-33 is/are rejected.
- 7) ☐ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Entry of Amendment

Applicant's amendment and Terminal Disclaimer filed on July 12, 2001, as Papers No. 6 & 7, are acknowledged. Claims 6 and 23-29 have been canceled by the applicant, thus claims 1-5, 7-22 and 30-35 are currently pending.

Prior Rejections or Objections

The following comments pertain to the rejections or objections in the most recent Office action, Paper No. 4, mailed on Nov. 22, 2000. Rejections under 35 U.S.C. 112, 102 and 103 are withdrawn, however, new grounds of rejection are presented below, resulting in the withdrawal from allowability of claims 13-22 and 30-33.

Claim Rejections - 35 USC § 112

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 recites the limitation "fluid delivery member" in line 2. There is insufficient antecedent basis for this limitation in the claim. The examiner suggests changing "delivery" to "receiving" to correct this.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 13-14, 16-20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Storm,III (4,140,130).

As to claims 1-3 and 5, Storm discloses an apparatus comprising:

a fluid delivery member (Figure 15, # 98 which receives the fluid and delivers it to the electrode and then out through the exit port # 100) with a tissue interface surface (103) that remains conformable to a skin surface as the tissue interface surface is applied to a surface of the skin;

a fluid passage lumen (99) coupled to the fluid delivery member; and

a thermal energy delivery device (electrode 101) coupled to the fluid delivery member in a position to transfer thermal energy to an electrolytic medium (tap water which has sufficient impurities to be an ionic conductor) that passes through the fluid delivery member (col. 6, lines 4-65 and col. 12, line 33-col. 13, line 13).

Further to claims 2 and 3, Storm discloses that thermal energy delivery device is positioned in an interior of the fluid delivery member and at or adjacent to an exterior surface of the fluid delivery member (Figure 15).

As to claims 13 and 14, Storm discloses an apparatus essentially as claimed, and the examiner maintains that this configuration could inherently heat the skin and the underlying tissue (including collagen) resulting in the shrinking of it to create a tightening of the skin surface.

As to claims 16-19, Storm further discloses that at least a portion of the fluid receiving member is a flexible pliant bag (formed by a membrane), has a tissue

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interface surface and is flexible to permit it to conform to the skin surface as it is applied to the surface of the skin (col. 12, lines 54-67).

As to claims 20 and 22, Storm discloses the thermal energy delivery device (RF electrode 101) is positioned in an interior of the fluid receiving member (Figure 15 and col. 5, lines 52-62).

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 3-5, 7, 8, 10-19, 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwards (5,505,730).

As to claims 1, 3-5, Edwards discloses an apparatus comprising:

a fluid delivery member (Figure 2b, # 12) with a tissue interface surface (34) that remains conformable to a tissue surface as the tissue interface surface is applied to the tissue;

a fluid passage lumen (54) coupled to the fluid delivery member; and

a thermal energy delivery device (RF electrode 42) coupled to the fluid delivery member in a position to transfer thermal energy to an electrolytic medium (saline) that passes through the fluid delivery member (col. 4, line 16-col. 5, line 53).

Further to claim 3, Edwards discloses that thermal energy delivery device is positioned at an exterior surface of the fluid delivery member and is positioned at the tissue interface surface (on 34, see Figure 3 and col. 5, lines 17-67).

As to claim 7, Edwards discloses that the tissue interface surface (32) has a porous surface (open cell foam, col. 5, lines 17-30).

As to claim 8, Edwards discloses that at least a portion of the fluid delivery member is a membrane (38 and col. 5, lines 39-53).

As to claim 10, Edwards discloses a sensor (46) coupled to the fluid delivery member (col. 6, lines 15-20).

As to claim 11, Edwards discloses that the sensor is positioned on the printed circuit board which is located on conductive surface (34) which in turn is the outer surface of conforming member (32) which conforms to tissue (col. 5, lines 18-22 and 54-59 and col. 6, lines 13-20).

As to claim 12, Edwards discloses a feedback device coupled to the energy delivery device and the sensor and which is responsive to a detected characteristic (temperature) of a tissue site and provide a controlled delivery of the thermal energy (col. 7, lines 10-21).

As to claims 13-15, Edwards discloses an apparatus essentially as claimed, and the examiner maintains that this configuration could inherently heat the skin and the underlying tissue (including collagen) resulting in the shrinking of it to create a tightening of the skin surface (col. 4, line 64-col. 5, line 59).

As to claims 16-19, Edwards further discloses that at least a portion of the fluid receiving member is a membrane, has a tissue interface surface and is flexible to permit it to conform to the skin surface as it is applied to the surface of the skin (col. 5, lines 39-53).

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As to claims 21 and 22, Edwards discloses the thermal energy delivery device (RF electrode 42) is positioned in an exterior of the fluid receiving member (Figure 2, and col. 4, line 64-col. 5, line38).

Claims 13, 20, 22 and 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Eggers et al. (6,159,194).

As to claim 13, Eggers et al. disclose an apparatus for treating the skin, comprising;

a fluid receiving member (Figure 19, annular space between cannula 118 and outer sleeve 116 which extend to the end of the electrodes 104);

a thermal energy delivery device (electrodes 104) coupled to the fluid receiving member in a position to transfer thermal energy to an electrolytic medium (saline) that passes through the fluid delivery member ;

an electrolytic medium positionable in the fluid receiving member, the thermal energy delivery device being positioned in the fluid receiving member to transfer thermal energy to the electrolytic medium for therapeutic contraction of collagen underlying the surface of the skin (col. 2, lines 49-65, col. 5, lines 20-34 and col. 19, lines 1-29).

As to claims 20 and 22, Eggers et al. further disclose that the thermal energy device (RF electrodes 104) is positioned in an interior of the fluid receiving member (col. 9, lines 14-34 and col. 19, lines 13-29).

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As to claim 30, Eggers et al. disclose a method for tightening an external surface of the skin with an underlying collagen containing tissue, comprising:

- providing a thermal energy delivery device with an energy delivery surface;
- positioning the thermal energy delivery surface on external surface of the skin;
- creating a reverse thermal gradient through the surface of the skin to sufficiently heat an underlying collagen containing tissue, wherein a temperature of the external surface of the skin is lower than a temperature of an underlying collagen containing tissue;

- detecting a temperature of the external surface of the skin;
- heating the underlying collagen containing tissue in response to a detected temperature of the external surface of the skin; and

- tightening at least a portion of the external surface of the skin (col. 2, lines 61-65, col. 6, lines 23-65, col. 9, lines 6-34 and col. 19, lines 1-29). Note that the electrolytic fluid cools the surface of the skin in order to inherently create the reverse thermal gradient claimed.

As to claims 31-33, the method of claim 30 is essentially the same since the tightening of the skin is a result of the shrinkage of the underlying collagen tissue as provided by the RF generator, electrodes and controller (see also col. 10, lines 8-38).

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Allowable Subject Matter

Claim 34 and 35 are allowed.

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Edwards (5,569,241) discloses a thin layer ablation apparatus with a similar structure to the Edwards reference used above; Edwards (6,024,743) discloses a method an apparatus with a similar structure to the Edwards reference used above; and Edwards (5,800,429) discloses a noninvasive apparatus for ablating turbinates which reads on claims 1, 2, 5, 7, 8, 10-20 and 22


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 703-308-3520. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 703-308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

September 17, 2001


Roy Gibson
Patent Examiner
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